

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NEW YORK**

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ONY, INC.,

Plaintiff,

v.

CORNERSTONE THERAPEUTICS, INC.,  
et al.

Defendants.

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Case No. 11-cv-1027-WMS

**REPLY IN SUPPORT OF DEFENDANTS CORNERSTONE THERAPEUTICS, INC.  
AND CHIESI FARMACEUTICI S.P.A.'S MOTION TO DISMISS PLAINTIFF'S  
COMPLAINT**

ONY's Memorandum of Law in opposition to Defendants Cornerstone Therapeutics, Inc. and Chiesi Farmaceutici S.p.A's ("Defendants") Motion to Dismiss concedes that ONY failed to state claims for tortious interference and injunctive relief. ONY attempts to save its other claims by ignoring the allegations it actually asserted in its Complaint and asserting new allegations, presumably because it concedes that it otherwise failed to state claims upon which relief can be granted.

ONY argues that the article at issue (the "Article") is false not because its calculations or statistical analysis are flawed but because, in its opinion, Defendants selected the data improperly and failed to include length of stay ("LOS") data and to cite articles ONY believes are relevant and contradictory. Opp'n Mem. at 16-17. However, these alleged deficiencies are methodological decisions that are the prerogative of the authors of an academic or scientific article. If ONY believes that doctors and hospitals will make better decisions about which surfactant to purchase if they consider additional articles or data not discussed in the Article, "its solution is to augment rather than censor the available information." *OPA Amsterdam BV v. American Institute of Physics*, 973 F. Supp. 414, 428 (S.D.N.Y. 1997). In any event, such an argument is properly addressed to the potential purchasers of surfactants – not to a court. *Id.*

#### **I. ONY Failed to Allege an Actionable Claim under the Lanham Act.**

ONY failed to allege an actionable claim under the Lanham Act because the Article itself is not commercial speech and ONY did not allege that Defendants misrepresented the conclusions of the Article or the underlying study. Further, ONY failed to plead its Lanham Act claim with sufficient specificity.

##### **A. The Article is Not Commercial Speech.**

ONY's Complaint alleges only that Defendants' press releases, distribution of the Article, web postings and other references to the Article constitute commercial advertising and

promotion under Lanham Act and does not allege that the Article itself is commercial advertising or promotion. Compl. ¶ 74. Having recognized that its Lanham Act claim will fail if the Article itself is not considered commercial advertising promotion, ONY now asserts that the Article itself is commercial speech even though it failed to make such an allegation in its Complaint. Opp'n Mem. at 8.

The Supreme Court's definitions of commercial speech range from an "expression related solely to the economic interests of the speaker and its audience," *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 561 (1980), to "speech that does no more than propose a commercial transaction," *United States v. Edge Broad. Co.*, 113 S. Ct. 2696, 2703 (1993). Under either definition, the Article is only commercial speech if its singular purpose is to influence purchasing decisions regarding surfactants.

"[A] scientific article is protected non-commercial speech despite the potential for erroneous content." *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 456 (D.N.J. 2009). A scientific, academic article is primarily educational and not commercial in nature, even if it contemplates a commercial transaction. *See Gordon & Breach Science Publishers S.A v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1524-25 (S.D.N.Y. 1994); *Neurotron, Inc. v. Am. Ass'n of Electrodiagnostic Med.*, 189 F. Supp. 2d 271, 275-77 (D. Md. 2001); *see also Oxycal v. Jeffers*, 909 F. Supp. 719, 723-26 (S.D. Cal. 1995) (academic book containing false statements about the content of a vitamin was not actionable commercial speech because the commercial elements of the speech were intertwined with the non-commercial central message). Thus, a scientific article cannot be considered commercial speech. *Id.*

In *Gordon & Breach*, the issue before the court was whether academic articles were commercial speech when they were written by an officer of the defendant publishing companies

and contained specific conclusions suggesting that libraries consider the price per printed word when determining which journals to publish and that authors seek to publish articles in journals with low cost per character. 859 F. Supp. at 1524-25. The court held that the articles themselves were primarily academic and therefore fully protected expression under the First Amendment because they contained an academic analysis related to an issue of considerable public significance, and were only secondarily commercial advertising and promotion. *Id.* at 1541 (stating that scientific libraries' struggle to balance their stagnant budgets with escalating subscription costs was "an issue of considerable public significance"). The court dismissed plaintiff's claim under the Lanham Act based on the content of the articles themselves without providing an opportunity for discovery. *Id.* at 1543.

Similarly, here, the Article is primarily an academic analysis. The Article was published by Journal of Perinatology, a medical journal published for educational purposes and for the benefit of the medical field. The content of the Article unquestionably demonstrates that its main focus is educational, not commercial. The Article is composed of a discussion of the patients studied, the methods of analysis used, and the results of the study; comparisons of the results to related literature; an acknowledgement of the limitations of the study; and the hypothesis that the different mortality rates associated with the three surfactants may be related to differences in dosing. Decl. of J. Kevin Fee ("Fee Decl."), Ex. A. ONY inexplicably claims that "[o]bjectively, the Article is not discussing a matter of 'public debate,'" Opp'n Mem. at 16, but one can hardly imagine an issue of greater public concern than infant mortality rates. This subject is undeniably of greater public concern than library budgets. *See Gordon & Breach*, 859 F. Supp. at 1541. Further, the Article does not make any purchasing recommendations or even mention the trademarked names under which the three surfactants are sold. *See Bracco*, 627 F.

Supp. 2d at 457 (holding that scientific articles were not commercial speech where they reached scientific conclusions but did not advocate the purchase of a particular product over another).

Thus, even assuming that ONY's allegation that agents of Defendants actually wrote the Article is true, the authoring of the Article itself is not commercial speech and is therefore not actionable under the Lanham Act. *See Gordon & Breach*, 859 F. Supp. at 1541; *Bracco*, 627 F. Supp. 2d at 457.

**B. ONY's Claim Based on Defendants' Dissemination of and References to the Article is Insufficient Because it Does Not Identify a False or Misleading Depiction of the Article's Conclusions.**

Defendants do not dispute that dissemination of a scientific article may in some circumstances constitute actionable commercial speech. However, ONY's Complaint fails to allege an actionable claim under the Lanham Act based on Defendants' distribution of or discussion regarding the Article.

ONY complains that the ultimate conclusions the Authors drew from the study, which are the subjects of Defendants' dissemination of and references to the Article, are false and misleading because they are based on a faulty data set, which would have been clear if Defendants considered and discussed the LOS data and additional literature. Opp'n Mem. at 16-17. However, decisions regarding which patients to include in a study and what data and literature are relevant are methodological decisions that all academic authors must make, and which become integral parts of their expression. The alleged deficiencies in the Article are therefore matters of opinion, not fact, and are not actionable under the Lanham Act, which prohibits only false or misleading descriptions of or representations of **fact**. *See* 15 U.S.C. § 1125(a)(1)(B); *Groden v. Random House*, 61 F.3d 1045, 1051 (2d Cir. 1995).

Even if, as ONY seems to believe, LOS data must be discussed in any mortality study to demonstrate that the underlying data has not been manipulated, the audience for the Article, professionals in the neonatology field, will note the absence of the LOS data and question the validity of the data set and the conclusions. The Article clearly discloses what factors were considered when selecting patients and what other literature was considered relevant. *See* Fee Decl., Ex. A. Thus, the Article itself provides its audience with all of the information it needs concerning the bases of the study to evaluate whether the Article's conclusions are reliable.

ONY relies on *Vidal Sassoon v. Bristol-Myers Co.*, 661 F.2d 272 (2d Cir. 1981), in which the Second Circuit held that a specific advertisement that presented a misleading picture of consumer testing that had been performed was actionable under the Lanham Act. The defendant in that case had created an advertisement that stated that 900 women tested and rated defendant's product higher than plaintiff's for certain characteristics. *Id.* at 274. The testing subjects had not actually tested the products head-to-head, but instead had each ranked one product on a scale from poor, fair, good, very good, excellent, and outstanding for a number of characteristics. *Id.* In tabulating the results, Defendant had included only ratings of "excellent" and "outstanding," whereas there would have been a statistically insignificant difference between the two products' ratings if Defendant had also considered the "good" and "very good" ratings. *Id.* In holding that "where **depictions of** consumer test results or methodology are so significantly misleading that the reasonably intelligent consumer would be deceived about the product's inherent quality or characteristics, an action under § 43(a) may lie," the court focused on whether the advertisement properly described the underlying testing, not the reliability of the testing itself. *Id.* at 278 (emphasis added). Similarly, in *Groden*, the Second Circuit held that so long as the advertiser's

description of the conclusions in an underlying work of opinion are accurate, there is no claim under the Lanham Act. 61 F.3d at 1051.

Here, ONY never alleged that Defendants misstated or mischaracterized the conclusions of the Article. Thus, ONY failed to allege an actionable claim for false advertising based on Defendants' dissemination of and reference to the Article.

**C. ONY Failed to Meet the Heightened Pleading Requirements of Rule 9(b).**

ONY's Lanham Act claim must also be dismissed for failure to meet the pleading requirements of Rule 9(b). Not only has this Court previously held that the pleading requirements of Rule 9(b) apply to false advertising claims that sound in fraud, *Volunteer Firemen's Ins. Servs., Inc. v. McNeil and Co., Inc.*, 221 F.R.D. 388 (W.D.N.Y. 2004), but numerous other courts that have agreed. *See, e.g., Vanguard Prods. Grp. v. Merch. Tech., Inc.*, No. 07-CV-1405-BR, 2008 U.S. Dist. LEXIS 28885, \*10-12 (D. Or. Apr. 3, 2008); *CardioNet, Inc. v. Lifewatch Corp.*, No.: 07 C 6625, 2008 U.S. Dist. LEXIS 15941, \*6 (N.D. Ill. Feb. 27, 2008); *Pestube Sys., Inc. v. HomeTeam Pest Def., LLC*, No. CIV-05-2832-PHX-MHM, 2006 U.S. Dist. LEXIS 34337, \*13-14 (D. Ariz. May 24, 2006); *CollegeNet, Inc. v. Xap Corp.*, No. CV-03-1229, 2004 U.S. Dist. LEXIS 21059, \*7 (D. Or. Oct. 12, 2004). Similarly, though the Second Circuit has not addressed this precise issue, it has held that Rule 9(b)'s heightened pleading requirements apply to a claim that sounds in fraud, even if it is not framed as a fraud claim. *See Rombach v. Chang*, 355 F.3d 164 (2d Cir. 2004).

In *Volunteer Firemen's*, this Court required defendant's counterclaim alleging that plaintiff prepared, distributed, used, and published documents containing false and/or misleading statements that purported to compare plaintiff and its products with others and the products of others, including defendant, to be pled with particularity. 221 F.R.D. at 389, 393. Although the

Court noted that the counterclaim did not expressly so state, defendant's theory was that plaintiff "brazenly, willfully and wantonly" misrepresented the nature of the parties' products in order to defraud potential consumers. *Id.* at 390. Here, ONY claims that the Defendants engaged in an "orchestrated marketing campaign" through which they misrepresented the relative mortality rates associated with the parties' products to influence doctors' and hospitals' purchasing decisions. *See* Opp'n Mem. 10-11; Compl. ¶¶ 42, 43, 44, 46, 61, 73. This claim is virtually identical to the counterclaim at issue in *Volunteer Firemen's* and the Court should likewise apply the heightened pleading requirements of Rule 9(b).

Rule 9(b) requires that the Complaint: "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Anatian v. Coutts Bank Ltd.*, 193 F.3d 85, 88 (2d Cir. 1999). ONY alleged merely that "Defendants Chiesi and Cornerstone have issued press releases repeating the 'findings' of the Article, distributed copies of the same to physicians and hospitals, included the Article on their websites, and otherwise made reference to and repeated the false and misleading 'conclusions' contained therein." Compl. ¶ 73. This pleading is insufficient to meet the requirements of Rule 9(b) because ONY failed to identify who distributed copies of the Article, to whom the copies were distributed, or the specific references Defendants have made regarding the Article to which ONY objects. Indeed, ONY concedes that it has not pled its Lanham Act claim with specificity and states that it has moved to amend its Complaint to allege such particulars.<sup>1</sup> Opp'n at 19-20. Thus, ONY's claim for false advertising should be dismissed.

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<sup>1</sup> On February 3, 2012, ONY moved to amend its Complaint. Defendants will address the adequacy of the claims alleged in any future complaint after a proposed complaint is filed in accordance with Local Rule 15(a). As demonstrated in Defendants' Memorandum of Law in



## **II. Injurious Falsehood**

For the reasons set forth at pages 7-10 of Defendants Ramanathan, Bhatia, and Sekar's Reply Memorandum, the contents of which are hereby incorporated, ONY failed to allege a claim for injurious falsehood under New York law.

## **III. ONY's Claim Under General Business Law § 349 Fails to Allege Injury to Consumers or the Public Interest.**

ONY's claim under New York General Business Law § 349 must be dismissed because ONY failed to allege any consumer injury or actionable harm to the public interest. The parties agree that the gravamen of any complaint asserting a claim under § 349 must be consumer injury or harm to the public interest. Opp'n Mem. at 22; *Azby Brokerage, Inc. v. Allstate Ins. Co.*, 681 F. Supp. 1084, 1089 n.6 (S.D.N.Y. 1988).

ONY alleges that the Article and its promotional dissemination were directed to consumers because the target audience for both was hospitals and physicians who purchase or influence purchasing decisions for surfactants. Opp'n Mem. at 23. However, for the purpose of § 349, consumers are defined as individuals who "purchase goods and services for personal, family or household use." *Med. Soc'y of State of New York v. Oxford Health Plans, Inc.*, 790 N.Y.S.2d 79, 79 (1st Dep't 2005) (holding that practices directed at physicians were not consumer oriented); *see also In re Rezulin Prods. Liab. Litig.*, 390 F. Supp. 2d 319, 338 n.101 (S.D.N.Y. 2005). Actions directed at physicians and hospitals who may purchase surfactants are therefore not directed at consumers for the purpose of § 349.

ONY's reliance on alleged violations of Food and Drug Administration regulations regarding product efficacy claims to support its allegations that Defendants' actions harmed the public interest also fails. *See* Opp'n Mem. at 23. The Federal Food Drug and Cosmetic Act,

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Support of its Motion to Dismiss and this Reply, dismissal is appropriate for the claims included in ONY's current Complaint.

which regulates product efficacy claims, lacks a private right of action and therefore ONY cannot rely on it for the purpose of asserting a state-law consumer claim under § 349. *See* 21 U.S.C. § 337(a); *Verzani v. Costco Wholesale Corp.*, 2010 U.S. Dist. LEXIS 107699, \*8 (S.D.N.Y. Sept. 28, 2010) (holding that misbranding claim under FDCA could not be converted to claim under § 349); *see also Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 200 (2d Cir. 2005) (affirming district court's decision not to permit a claim under § 349 for violation of a statute with no private cause of action).

ONY relies on *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256 (2d Cir. 1995), in which the court held that plaintiff had demonstrated sufficient harm to the public where defendant gave false information to a regulatory public safety agency, which caused it to undertake unnecessary investigations and interfered with its decision making process and diverted another group that assures safety of electrical equipment from its normal activities. *Id.* at 264. In contrast, ONY has not alleged that any public safety entity was harmed by or diverted away from its public-safety role because of Defendants' actions.

The gravamen of ONY's Complaint is injury to ONY, not to consumers or the public interest. Thus, ONY's claim under § 349 should be dismissed. *See Winner Int'l v. Kryptonite Corp.*, No. 95-civ-247, 1996 U.S. Dist. LEXIS 2182, at \*2 (S.D.N.Y. Feb. 27, 1996).

#### **IV. ONY Concedes that Its Tortious Interference and Injunctive Relief Claims are Deficient.**

ONY concedes that its claim for tortious interference is insufficient because it failed to allege specific contracts or relationships with which Defendants interfered. Opp'n Mem. at 24. ONY also concedes that an injunction is a remedy and not a cause of action. *Id.* Therefore the

Court should dismiss ONY's claims for tortious interference and injunctive relief for failure to state a claim upon which relief can be granted.<sup>2</sup>

**V. Conclusion**

For the foregoing reasons, it is respectfully submitted that all claims in ONY's Complaint asserted against Defendants be dismissed for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

DATED: February 13, 2012

Respectfully submitted,

/s/ J. Kevin Fee

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<sup>2</sup> As discussed above, ONY moved to amend its Complaint, including by adding allegations in support of its tortious interference claim. Defendants will address the adequacy of all claims alleged in a future complaint after a proposed complaint is filed. Having failed to allege its tortious interference claim sufficiently in the current Complaint, dismissal is appropriate for the existing claim.

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK**

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Plaintiff,

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CORNERSTONE THERAPEUTICS, INC., *et al.*

Defendants.

Case No. 1:11-cv-01027-WMS

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on February 13, 2012, I electronically filed the foregoing Reply in Support of Motion to Dismiss by Defendants Cornerstone Therapeutics, Inc. and Chiesi Farmaceutici S.p.A. with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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